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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,312	12/04/2003	Dieter Hochrainer	821-011725-US(PAR)	9650

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EXAMINER
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LOPEZ, AMADEUS SEBASTIAN

ART UNIT	PAPER NUMBER
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3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/16/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/728,312	Applicant(s) HOCHRAINER, DIETER	
	Examiner Amadeus S. Lopez	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Response to Amendment***

1. Regarding the first stated ground for rejection under 35 USC 112, second paragraph, the examiner acknowledges the removal of the phrase "of the sort" and hereby removes the rejection regarding this matter.

### ***Response to Arguments***

Applicant's arguments filed 12/11/2006 have been fully considered but they are not persuasive. The applicant makes the argument that claims 21 and 22 are in Jepson format where "everything recited in claim 21 and 22 above the last subparagraph describes prior art, and the last paragraph describes the improvement provided by the invention." Again it is repeated that in claim 21, lines 14-18 and claim 22 in lines 11-15, the capsule member is recited as being configured to enable a capsule to vibrate longitudinally and also transversely whereas the last line in claims 21 and 22 recite that the chamber is configured to allow essentially no transverse movement of the capsule within the capsule chamber. The two statements within the claims contradict each other and the claims are maintained as being indefinite and stand rejected under 35 USC 112, second paragraph.

The argument made regarding the rejection of claims 21 and 22 under 35 USC 103(a) as being unpatentable over Valentini et al (4069819) have been fully considered and are persuasive. The applicant clearly and effectively argues that the raised elements of Valentini et al may include raised elements, but they are not adapted to limit

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transverse movement of the capsule, as they are in the improvement provided by the invention.

However, the argument made regarding the rejection of claims 21 and 22 under 35 USC 103(a) as being unpatentable over Valentini et al in view of Kladders is not persuasive. The applicant makes the argument that "it would appear that the raised elements 7 of Kladders are similarly adapted to limit longitudinal movement of the capsule within the capsule chamber, and not to limit transverse movement." In fact, the raised elements (7) of Kladders' device are shown in figure 2, which is a cross-sectional view along the line A-A in Fig.1. To give the applicant perspective, this view looks down the longitudinal axis of the device with the ribs (7) lining the inside surface of the capsule chamber 6 intended to limit transverse movement of the capsule 15 as stated in Col. 3, lines 47-49. Therefore the rejection as set forth in the previous action is maintained and hereby repeated.

### ***Specification***

The disclosure is objected to because of the following informalities:

On page 20 in line 18, the number "(2)" after the word "spikes" should be deleted and replaced by -- (20) --.

On page 21 in line 4, the number "(18)" after the word "button" should be deleted and replaced by -- (8) --.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 21, lines 14-18, the capsule chamber is recited as being configured to enable a capsule to vibrate longitudinally and also transversely whereas the last line in claim 21 recites essentially no transverse movement of the capsule within the capsule chamber.

In claim 22, lines 11-15, the capsule chamber is recited as being configured to enable a capsule to vibrate longitudinally and also transversely whereas the last line in claim 22 recites essentially no transverse movement of the capsule within the capsule chamber.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. ('819) in view of Kladders ('114).

As to claim 21, Valentini et al. disclose an improved combination comprising a capsule and a medicinal powder inhaler device (figs.1-6) of the sort comprising, (a) a

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generally cylindrical capsule (C) having a longitudinal axis and containing a pharmaceutically active inhalable medicament, and (b) a medicinal powder inhaler device of the sort comprising, (1) a capsule chamber (B) for receiving the capsule, said capsule chamber having an inlet (H) proximate a first end, for admitting air into the chamber and an outlet (see apertures at bottom of mouthpiece A in fig.5), proximate a second end, which communicates with a mouthpiece (A), the axis of the chamber being the line running between the first and second ends, by means of which mouthpiece a patient can draw by inhalation a stream of air which flows from the inlet, through the capsule chamber, wherein it admixes with medicament which has been released from a capsule that has been received by the chamber, thence through the outlet and finally from the mouthpiece from whence the patient may inhale the mixture of air and medicament, said capsule chamber being configured to enable a capsule received therein to vibrate longitudinally (in the direction of air flow) and also transversely (at right angles to the direction of flow) while remaining aligned substantially parallel to the chamber axis when air is caused to pass through the chamber in response to inhalation by the patient, and (2) means (D) for piercing a capsule placed into the capsule chamber, to thereby release medicament from the capsule into the capsule chamber, wherein said improvement comprises the inclusion of raised elements (in fig.5, see angled raised surface within which piercing means D are recessed) on either the inner surface of said capsule chamber or the outer surface of said capsule, which raised elements align the axis of the capsule with the axis and the capsule chamber and which

constrain the capsule, when it vibrates within the capsule chamber, to move back and forth along its longitudinal axis.

The raised elements of Valentini et al lack the teaching of being adapted to allow the capsule to move back and forth along its longitudinal axis with essentially no transverse movement when it is vibrated. Kladders, in a powder inhaler teaches raised elements (#7 and col.3, lines 47-49) on the inner surface of the capsule chamber for the purpose of limiting the play of the capsule within the chamber (6). The raised elements 7 of Kladders' device are shown in figure 2, which is a cross-sectional view along the line A-A in Fig.1. To give the applicant perspective, this view looks down the longitudinal axis of the device with the ribs (7), lining the inside surface of the capsule chamber 6 to limit transverse movement of the capsule (15).

It would have been obvious to modify the inner surface of the capsule chamber of Valentini et al. to include raised elements thereon because it would have provided a means for limiting the play of the capsule and thereby allowing essentially no transverse movement of the capsule within the chamber as taught by Kladders.

Claim 22 is substantially equivalent in scope to claim 21 and is included in Valentini et al. as modified by Kladders for the reasons set forth above with respect to claim 21.

### ***Conclusion***


6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 6810872, US 5996577, US 5492112, and US 6948492. The balance of the art is cited to show relevant powder inhalers.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Amadeus S Lopez  
Examiner  
Art Unit 3771  
February 12, 2007

ASL

  
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2/13/07